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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,132	10/29/2001	Donald E. Bobo JR.	CVG-5637	2468

7590 04/18/2008

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ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
04/18/2008	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 3222008

Application Number: 10/021,132
Filing Date: October 29, 2001
Appellant(s): Bobo, Donald et al

Rajiv Yadav
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 21, 2007.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendments after final have been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

Claim 31 contain(s) substantial errors as presented in the Appendix to the brief. Accordingly, claim 31 is correctly written in the Appendix to the Examiner's Answer.

(8) Listing of Evidence Relied Upon

The following is a listing of the prior art of evidence (e.g. patents, publications Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

Number (Title)	Name	Date
5,725,523	Mueller	March 10, 1998
5,807, 388	Jeevanandam et al	September 15, 1998
6,161,553	Cox et al	December 19, 2000
6,283,951	Flaherty et al	September 4, 2001
5,645,199	Jenkins et al	November 11, 2003
2001/0049497	Kalloo	December 6, 2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 36-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure and the disclosure or amended is silent on "supportively engaging the atrial septum with the medicament delivery catheter …"

Claims 42-44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Flaherty et al.

Claims 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, Cox et al, and Kalloo et al. Flaherty et al teach a method of

myocardial drug delivery. Jenkins et al teach a method of crossing the septum as claimed (column 1, line 20 to column 2, line 54). Cox et al teach the use of means to seal the tissue around an internal chamber ablation device to prevent bleeding when working on a beating heart. Kalloo et al teach the use of a dual balloon stabilizing means to aid in the placement of a surgical device. It would have been obvious to the artisan of ordinary skill to, in order to access the myocardium transvenously, to employ the method of Jenkins et al, since Flaherty et al teach no details of the transvenous placement method; and in order to wedge the probes as in the method of Jenkens et al, to employ the balloons of Kalloo et al, since this would both stabilize the devices as well as seal the opening, which is desirable, since this prevents bleeding when the procedure is performed on a beating heart, as taught by Cox et al, thus producing a device and method such as claimed.

Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, and Mueller ('523). The teachings of Flaherty et al and Jenkins et al and the motivations for combination thereof are substantially as set forth above. Mueller ('523) teach sealing to the cardiac tissue using a vacuum port before creating a channel in the tissue. It would have been obvious to the artisan of ordinary skill to employ the combined drug injection of method of Flaherty et al and Jenkins et al in the method of Mueller ('523) since this is desirable to help maintain the channels, as taught by Flaherty et al, thus producing a method such as claimed.

Claims 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flaherty et al in combination with Jenkins et al, and Mueller ('523) as applied to claims 39 and 40 above, and further in view of Jeevanandam et al. Jeevanandam et al teach the use of multiple vacuum ports

to secure a channel-forming device to the cardiac wall so as to form chambers therein. It would have been obvious to the artisan of ordinary skill to provide multiple ports, as taught by Jeevanandam et al, since this provides secure fixation and to provide four ports, since the number of ports can be varied as desired, as taught by Jeevanandam et al, thus producing a method such as claimed.

(10) Response to Argument

I & II) Rejection Of Claims 36-38 As Not Having Support in the Originally Filed Disclosure Under 35 USC 112 1st Paragraph

Applicant points to the disclosure at page 18 to argue support for the claim language. However the claim term "medicament delivery catheter" does not per se appear in the originally filed disclosure, thus the claim language cannot find support in this cited passage alone. The examiner, in analyzing the method claimed in view of the specification, especially with respect to Figures 41a-c and 42a-c, and the written disclosure attendant thereto, notes that if the term "medicament delivery catheter" is construed to be the " device 300' " set forth in the disclosure, this would require that **after** the device 300' is "supportively engaging" and thus attached to the atrial septum via the balloons thereon, it is **then** further advanced, which would cause tearing and destruction of the atrial septum, which is still attached, by virtue of the device 300' "supportively engaging" it, as the device 300' is being advanced. Thus as this would have a catastrophic effect on the health of the patient, the originally filed disclosure, drawn to medically treating the beating heart, rather than destroying it, possibly beyond repair, is not a concept that can fairly be read thereinto. It appears that the claim was intending to be crafted to recite that the inner catheter, the ablating member 310' (which is the element which actually delivers the

medicament), as that portion which is advanced after the outer catheter is sealingly joined to the atrial septum.

III) Claims 42-44 Are Properly Rejected Under 35 U.S.C. 102(e) As Being Unpatentable Over Flaherty et al

Appellants argue in essence, because the balloon of Flaherty et al is disclosed as porous (see the instant Brief, page 12, first full paragraph), it cannot show sealing as claimed (see the instant Brief, the remainder of page 12, and the paragraph bridging pages 12 and 13).

While the examiner maintains that the disclosure at column 2, lines 11-14 of Flaherty teaches the possession of the concept of non-porous balloons by one of ordinary skill in the art, there are additional considerations to examine. Firstly, the originally filed disclosure states that "a sealing balloon may be used to isolate the region and prevent medicament washout" (see the originally filed disclosure, paragraph [0016]), thus if the balloon prevents washout, it can be considered "sealing", as the examiner has been unable to find any disclosure that indicates that "sealing" should be read as preventing even one molecule of medicament from escaping from the channel, although the requirement that the sealing member "isolate the tissue" (see originally filed claim 23) could be construed to indicate that within the spectrum of meanings encompassed by sealing, the extent of seal inferred by the term "sealing" is more towards the end of the spectrum indicating a perfect seal rather than an imperfect one. Thus, while a perfect seal might be the ideal, there is no disclosure to indicate that this is the only definition readable into the term "sealing" as used in the originally filed disclosure.

Turning now to the Flaherty et al disclosure, the problem of wash-out, and the attendant global side effects that arise from administering more of the treating material to remedy the problem of wash-out are discussed from column 2, line 55 to column 3, line 8, and the desire to

remedy these problems is discussed at column 3, lines 40-45. Thus clearly Flaherty et al desire to avoid wash-out thus the porous balloon in the embodiment of Figure 6 must be construed to provide a degree of "sealing" which at least partially overlaps the spectrum of meaning encompassed by the term "sealing" as used in the claims at bar. Quite apart from this, Flahertey et al disclose that the balloon has a "porous region, such as a plurality of holes **226**, a permeable membrane and the like preferable arranged to provide a predetermined flow pattern through the balloon **218** into the tissue region **220**." (see column 12, lines 39-51). Thus only a region of the balloon and not its entirety, need be provided with the structure to release the medication. Given the set forth disclosures and given that Flaherty et al must be read as by one of ordinary skill in the art, the clear teaching here is that the desire is to deliver "a drug directly and precisely into a selected remote tissue region" (see Flaherty et al column 14, lines 29-30) and not merely allowed to leak out to the remainder of the body which is not desired to be exposed to the medicament. This would lead one of ordinary skill in the art to locate the porous region of the balloon towards the distal portion of the balloon, leaving the proximal portion, which is exposed to the general blood pool that is still circulating throughout body non-porous. Thus it is the examiner's view that the teaching of a "sealing" balloon, howsoever appellant would chose to construe the meaning thereof in the claims at bar, is fairly contained within the four corners of the Flaherty et al reference.

With regard to claim 43, as Flaherty et al teach expanding or opening the channel via the inflation of the balloon, as seen at column 13, lines55-61: "The guide wire assembly **162** may then be deployed transvascularly to access the selected tissue region **220**, similar to the process previously described. The drug delivery catheter **214** may then be advanced over the guidewire

assembly **162** until it enters the tissue region **220**. The balloon **218** may then be inflated…" As the opening is started by the guide wire; further opened by the catheter and fully opened by the expanding balloon; thus, since in Flaherty et al the balloon is pressed against the opening during the final part of the opening forming process, the method of Flaherty et al does read on the language of claim 43. Similarly, since the medicament is not introduced until the balloon at least until inflation has commenced, and the medicament is delivered as a result of some inflation of the balloon, the language of claim 44 is also met thereby.

IV)Claims 36-38 Are Properly Rejected Under 35 U.S.C. 103 As Being Unpatentable Over Flaherty et al in combination with Jenkins et al, Cox et al, and Kalloo et al

Appellant argues, with respect to the teachings of Cox et al, that while sealing means are taught, these sealing meas are separate from the interventional device around which the tissue is sealed; with regard to Kalloo et al, that the balloons therein cannot be bodily incorporated into a device for operating on the heart; and with respect to Jenkins et al, that the catheter which is supportively engaging the atrial septum at an opening therein is not a medicament delivery catheter. However these do not speak to the references as combined in the rejection. As already set forth in the rejection, one of ordinary skill in the art would look to Jenkins et al, since Flaherty et al teach no details of the transvenous placement method, and would thus employ this method and would thus wedge the probes, as also taught by Jenkins et al (see column 6, lines 49-54). and would further employ the balloons of Kalloo et al, as this would both stabilize the device and seal the opening (see Kalloo et al, page 2, column 2, paragraph [0031]), which sealing is desirable as taught by Cox et al (see column 15, line 56-64), this aspect of the rejection was explicitly set forth on page 3 of the final rejection (see especially lines 1-10). Thus while Cox et al teach various sealing devices associated with separate tools, that does not remove therefrom

the explicit teaching that sealing is desirable, especially when working on a beating heart. While the balloons of Kalloo et al may not be bodily incorporated into the device of Flaherty et al, this does not remove therefrom the teaching that such balloons provide a sealing and anchoring function. Nor does it create in the originally filed disclosure any disclosure relating to the particular "design considerations" relating to balloons for intracardiac sealing, which would be necessary for the instant disclosure to be enabled for such balloons were such "design considerations" not already well within the scope of one of ordinary skill in the art (which the examiner believes they are). And lastly, while Jenkins et al do not teach drug delivery, it does not remove therefrom the pertinent teachings regarding trans venous delivery of interventional devices. In view of the foregoing, the rejection of claims 36-38 as set forth above is proper.

V) Claims 36-38 Are Properly Rejected Under 35 U.S.C. 103 As Being Unpatentable Over Flaherty et al in combination with Jenkins et al and Mueller et al ('523)

Here appellant merely argues that Flaherty et al do not teach providing the sealing function which the examiner has already demonstrated as present therein in section III) above. As such these arguments are not convincing for the reasons set forth above. Similarly, the remarks drawn to the affect of the suction of Mueller et al ('521) on the balloon are not convincing as they are predicated on the entire balloon being porous, when the balloon thereof is taught as being non-porous over some portions thereof, as also set forth above in section III).

VI)Claim 41 is Properly Rejected Under 35 U.S.C. 103 As Being Unpatentable Over Flaherty et al in combination with Jenkins et al and Jeevanandam et al

The basis of appellant's argument is that since Jeevanandam et al teach "suction cups" rather than "vacuum ports" the reference cannot be used to render obvious claim 41, which requires "vacuum ports". This argument is not convincing, as, absent a means plus function recitation, applicant cannot restrict the recitation in the claim to only those elements disclosed in

the specification or their equivalents. Further, even assuming the claim language could be construed to omit suction cups, the suction cups of Jeevanandam et al are only an exemplary embodiment of a gripping means which may be used therein (see column 2, lines 60-61), and one of ordinary skill in the art would immediately understand that any means for applying suction, such as vacuum ports would perform equally well. Thus this argument is not convincing.

(11) Related Proceedings Appendix

NONE

(12) Conclusion

It is the examiner's firm opinion that the appealed claims are not patentable for the reasons argued above. Appellant has presented no convincing argument as to why the rejections set forth above are not obvious or proper. Therefore, it is respectfully submitted that the final rejection be affirmed.

Respectfully submitted,

/david shay/

Primary Examiner, Art Unit 3735

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April 18, 2008

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APPENDIX A

Claim 31. The method of claim 28 further comprising delivering the beam of light energy to the eye with a laser delivery system.